

# VAPRA Capsules (OMEPRAZOLE 20mg)

## Composition:

Each capsule contains:

Omeprazole ..... 20mg

## Indications:

- Duodenal ulcer
- Gastric ulcer
- Reflux oesophagitis
- Zollinger- Ellison syndrome
- Prevention of recurrence in severe reflux oesophagitis.

## Dosage:

**Duodenal ulcer:** The recommended oral dosage is 20 mg (1 capsule) once daily. Symptom relief is rapid and healing occurs within two weeks in most cases. For those patients who may not have fully healed after the initial course, healing usually occurs during a further 2 weeks treatment period. In patients refractory to other treatment regimens, 40 mg (2 capsules) once daily has been used and healing achieved, usually within 4 weeks.

**Gastric ulcer:** The recommended oral dosage is 20 mg (1 capsule) once daily. Ulcer symptoms relief is rapid and healing occurs within 4 weeks in most cases. For those patients who may not have fully healed after the initial course, healing usually occurs during a further 4 weeks treatment period. In patients refractory to other treatment regimens, 40 mg (2 capsules) once daily has been used and healing achieved, usually within 8 weeks.

**Reflux Oesophagitis:** The recommended oral dosage is 20 mg (1 capsule) once daily. Ulcer symptoms relief is rapid and healing occurs within 4 weeks in most cases. For those patients who may not have fully healed after the initial course, healing usually occurs during a further 4 weeks treatment period. . In patients with severe reflux oesophagitis, 40 mg (2 capsules) once daily has been used and healing achieved, usually within 8 weeks.

## Prevention of recurrence in severe reflux oesophagitis maintenance therapy:

The recommended oral dosage is 20 mg (1 capsule) once daily to avoid recurrence in patients with severe reflux oesophagitis. In the event of recurrence the dose can be increased to 40 mg (2 capsules) once daily.

**Zollinger Ellison Syndrome:** The recommended initial dose is 60 mg (3 capsules) once daily. The dosage should be adjusted individually and treatment continued as long as is clinically indicated. All patients with severe disease and inadequate response to other therapies have been effectively controlled and more than 90% of the patients maintained on doses of 20-120 mg daily. With doses above 80 mg daily, the dose should be divided and given twice daily.

**Impaired renal and liver function:** Dose adjustment in patients with impaired renal or liver function is not required.

**Children:** Its use in children is not recommended.

**Elderly patients:** No dosage adjustment is necessary for elderly.

**Contraindications:** There are no known contraindications to the use of Vapra.

**Precautions:** When gastric ulcer is suspected, the possibility of malignancy should be excluded as treatment may alleviate symptoms and delay diagnosis.

**Use in pregnancy and lactation:** As with all new drugs, Vapra should not be given during pregnancy and lactation unless its use is considered essential. Animal studies have not shown evidence of any hazard from the administration of Vapra during pregnancy and lactation and there is no evidence of fetal toxicity and teratogenic effect.

**Interactions:** Vapra can prolong the elimination of diazepam and phenytoin, drugs that are metabolized by oxidation in liver. Monitoring of patients also receiving warfarin or phenytoin is recommended and a reduction of dose of phenytoin and warfarin may be necessary. However concomitant treatment with Vapra daily did not change the blood concentration of phenytoin in patients on continuous treatment with phenytoin. No interaction with propranolol, metoprolol, theophylline, lidocaine, quinidine, and amoxicillin has been found, but interactions with other drugs also metabolized via the cytochrome P450 enzyme system cannot be excluded. No interaction with concomitantly administered antacids has been found.

**Side Effects:** Vapra is well tolerated. The following events have been reported, but in most cases a consistent relationship between these events and treatment with Vapra has not been established.

**Dermatologic:** Rarely, rash, urticaria, and pruritus.

**Musculoskeletal:** In isolated cases, arthralgia, muscular weakness and myalgia.

**Peripheral and central nervous system:** Headache, dizziness, paresthesia, somnolence, insomnia and vertigo. In isolated cases, reversible mental confusion, agitation, depression, and hallucination, predominantly in severely ill patients.

**Gastrointestinal:** Constipation, abdominal pain, nausea/vomiting and flatulence. In isolated cases, stomatitis, and gastrointestinal candidiasis.

**Endocrine:** In isolated cases, gynecomastia.

**Hematologic:** In isolated cases, Leukopenia, and thrombocytopenia.

**Hepatic:** In isolated cases, increased liver enzymes with or without increases bilirubin values.

**Other:** Rarely, malaise. In isolated cases, peripheral edema, blurred vision and taste perversion.

**Overdosage:** There is no information available on the effects of over dosage in man and specific recommendations for treatment cannot be given.

Single oral doses of up to 160 mg and dosages of up to 360mg / day have been well tolerated.

## How Supplied:

Pack of 14 capsules.

ہدایات:

## Instructions:

Use as directed by the physician.

Store in a cool, dry place and protect from light.

Keep out of the reach of children.

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ٹھنڈی اور خشک جگہ پر رکھیں۔

دوا کو روشنی، گرمی اور نمی سے بچائیں۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔



Manufactured By:

Vega Pharmaceuticals (Pvt.) Ltd.

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